CLAIMS

1. A sustained release oral pharmaceutical dosage formulation comprising:

(a) a core comprising:

(i) an opioid analgesic;

(ii) at least one pharmaceutical excipient; and

(b) a delayed release coating surrounding the core comprising:

(i) a first enteric coating agent;

(ii) a second enteric coating agent;

(iii) optionally a plasticizer;

(iv) optionally an inert processing aid; and

(c) an immediate release drug layer comprising:

(i) an opioid analgesic;

(ii) a binder; and

(d) optionally a cosmetic coating.

2. The sustained release dosage formulation as defined in claim 1 wherein the opioid analgesic is selected from the group consisting of buprenorphine, codeine, dihydrocodeine, dihydromorphine, hydromorphone, morphine, oxycodone and salts of the foregoing.

3. The sustained release dosage formulation as defined in claim 2 wherein the opioid analgesic is oxycodone or a pharmaceutically acceptable salt thereof.

4. The sustained release dosage formulation as defined in claim 1 wherein the pharmaceutical excipient in the core is selected from the group consisting of binders, diluents, lubricants, emulsifiers, osmopolymers, osmotic agents, glidants, flavoring agents and combinations of the foregoing.

5. The sustained release dosage formulation as defined in claim 1 wherein the pharmaceutical excipient in the core comprises a binder and a diluent.

6. The sustained release dosage formulation as defined in claim 5 wherein the pharmaceutical excipient in the core further comprises a glidant and a lubricant.

7. The sustained release dosage formulation as defined in claim 5 wherein the binder is an osompolymer.

8. The sustained release dosage formulation as defined in claim 5 wherein the binder is water soluble and has a viscosity of greater than 50,000 mPa when tested in a 2% aqueous solution at 20° C.

9. The sustained release dosage formulation as defined in claim 5 wherein the binder is water soluble and has a viscosity of greater than 75,000 mPa when tested in a 2% aqueous solution at 20° C.

10. The sustained release dosage formulation as defined in claim 1 wherein the first enteric coating agent begins to dissolve at a pH of about 5 to about 6 and the second enteric agent begins to dissolve at a pH of above 7 or is degraded in the gastrointestinal tract.

11. The sustained release dosage formulation as defined in claim 1 wherein the first enteric coating agent begins to dissolve at a pH of about 6 to about 7 and the second enteric agent begins to dissolve at a pH of above 8 or is degraded in the gastrointestinal tract.

12. The sustained release dosage formulation as defined in claim 10 wherein the second enteric agent begins to dissolve at a pH of about 11 to about a pH of 12.

13. The sustained release dosage formulation as defined in claim 10 wherein the ratio of first enteric agent to the second enteric agent is about 1:5 to 5:1.

14. The sustained release dosage formulation as defined in claim 13 wherein the ratio of first enteric agent to the second enteric agent is about 1:2 to about 1:4.

15. The sustained release dosage formulation as defined in claim 1 wherein the inert processing aid comprises about 20 to about 70 percent of the total weight of the delayed release coating.

16. The sustained release dosage formulation as defined in claim 15 wherein the inert processing aid comprises about 30 to about 60 percent of the total weight of the delayed release coating.

17. A sustained release oral pharmaceutical dosage formulation comprising:

(a) a core comprising:

(i) an opioid analgesic;

(ii) a diluent;

(iii) a binder that is water soluble and has a viscosity of greater than 50,000 mPa when tested in a 2% aqueous solution at 20° C; and

(b) a delayed release coating surrounding the core comprising:

(i) a first enteric coating agent that begins to dissolve at a pH of about 5 to about 6;

(ii) a second enteric coating agent that begins to dissolve at a pH of above 8;

(iii) an inert processing aid;

(iv) optionally a plasticizer; and

(c) an immediate release drug layer comprising:

(i) an opioid analgesic;

(ii) a binder; and

(d) optionally a cosmetic coating.

18. The sustained release dosage formulation as defined in claim 17 wherein the opioid analgesic is selected from the group consisting of buprenorphine, codeine, dihydrocodeine, dihydromorphine, hydromorphone, morphine, oxycodone and salts of the foregoing.

19. The sustained release dosage formulation as defined in claim 18 wherein the opioid analgesic is oxycodone or a pharmaceutically acceptable salt thereof.

20. The sustained release dosage formulation as defined in claim 17 wherein the binder in the core has a viscosity of greater than 75,000 mPa when tested in a 2% aqueous solution at 20° C.

21. The sustained release dosage formulation as defined in claim 17 wherein the first enteric coating agent begins to dissolve at a pH of about 6 to about 7 and the second enteric agent begins to dissolve at a pH of above 9.

22. The sustained release dosage formulation as defined in claim 17 wherein the second enteric agent begins to dissolve at a pH of about 11 to about a pH of 12.

23. The sustained release dosage formulation as defined in claim 17 wherein the ratio of first enteric agent to the second enteric agent is about 1:5 to 5:1.

24. The sustained release dosage formulation as defined in claim 17 wherein the ratio of first enteric agent to the second enteric agent is about 1:2 to about 1:4.

25. The sustained release dosage formulation as defined in claim 17 wherein the inert processing aid comprises about 20 to about 70 percent of the total weight of the delayed

release coating.

26. The sustained release dosage formulation as defined in claim 25 wherein the inert processing aid comprises about 30 to about 60 percent of the total weight of the delayed release coating.

27. A sustained release oral pharmaceutical dosage formulation consisting essentially of:

(a) a core comprising:

(i) oxycodone or a pharmaceutically acceptable salt;

(ii) a diluent;

(iii) a binder that is water soluble and has a viscosity of greater than 50,000 mPa when tested in a 2% aqueous solution at 20° C;

(iv) a lubricant;

(v) a glidant; and

(b) a delayed release coating surrounding the core consisting essentially of:

(i) a first enteric coating agent that begins to dissolve at a pH of about 5 to about 6 or is degraded in the gastrointestinal tract;

(ii) a second enteric coating agent that begins to dissolve at a pH of above 7 or is degraded in the gastrointestinal tract;

(iii) about 20 to about 70 percent of the total weight of the delayed release coating of an inert processing aid;

(iv) optionally a plasticizer; and

(c) an immediate release drug layer consisting essentially of:

(i) oxycodone or a pharmaceutically acceptable salt;

(ii) a binder; and

(d) optionally a cosmetic coating.

28. The sustained release dosage formulation as defined in claim 27 wherein the binder in the core has a viscosity of greater than 75,000 mPa when tested in a 2% aqueous solution at 20° C.

29. The sustained release dosage formulation as defined in claim 27 wherein the first enteric coating agent begins to dissolve at a pH of about 6 to about 7 and the second enteric agent begins to dissolve at a pH of above 8 or is degraded in the gastrointestinal tract.

30. The sustained release dosage formulation as defined in claim 27 wherein the second enteric agent begins to dissolve at a pH of about 11 to about a pH of 12.

31. The sustained release dosage formulation as defined in claim 27 wherein the ratio of first enteric agent to the second enteric agent is about 1:5 to 5:1.

32. The sustained release dosage formulation as defined in claim 27 wherein the ratio of first enteric agent to the second enteric agent is about 1:2 to about 1:4.

33. The sustained release dosage formulation as defined in claim 27 wherein the inert processing aid comprises about 30 to about 60 percent of the total weight of the delayed release coating.